

REMARKS

Claims 15-21 are active in this application.

Applicants would like to thank Examiner Gambel for the helpful and courteous discussion with their undersigned Representative on November 6, 2003. During this discussion, various amendments and arguments were discussed to address the rejections under 35 U.S.C. § 112, second paragraph, 35 U.S.C. § 102(b), 35 U.S.C. § 102(e), and 35 U.S.C. § 103(a). The context of this discussion is believed to be accurately and completely reflected in the amendments and remarks set forth herein.

The present invention provides, in part, a pharmaceutical composition having antithrombotic efficacy comprising a pharmaceutically acceptable carrier and a monoclonal antibody having the following properties:

- (a) the monoclonal antibody binds to human von Willebrand Factor; and
- (b) the monoclonal antibody inhibits binding between a monoclonal antibody produced by hybridoma and human von Willebrand Factor, wherein the hybridoma is selected from the group consisting of FERM BP-5248 (AJvW-2), FERM BP-5250 (AJvW-4) or a variant of said hybridoma. Applicants submit that, for the reasons cited below, none of the art of record discloses or suggests the presently claimed invention.

The rejections of (a) Claims 15 and 16 under 35 U.S.C. §102(b) over Benson et al; (b) Claims 15 and 16 under 35 U.S.C. §102(b) over Fujimura et al; (c) Claims 15, 16, and 21 under 35 U.S.C. §102(e) over Scarborough; and (d) Claims 15, 16, and 21 under 35 U.S.C. §103(a)

over Scarborough, Benson et al [cited as second instance of Scarborough in rejection header on page 6], and Fujimura et al are obviated by amendment.

On page 5 of paper number 7 in numbered paragraph 11, the Examiner states: "For examination purposes and given the broadest reasonable interpretation of the claims, the recitation of "variant" reads on antibodies that [bind] von Willebrand factor." Accordingly, it is Applicants understanding that the rejections over Benson et al, Fujimura et al, and Scarborough are based on the broad interpretation of "variant" as qualifying the monoclonal antibody. Consistent with this understanding is that Benson et al, Fujimura et al, and Scarborough each disclose von Willebrand factor-specific monoclonal antibodies that fall outside the scope of the claimed, combined limitations (a) and (b).

Applicants wish to bring the Examiner's attention to page 19, lines 7-16 of the specification, which clearly indicate that the term "variant" relates to the hybridoma and seeks to retain coverage of monoclonal antibodies resulting from any variation in the progeny of these hybridomas. To clarify the present invention and the scope entitled thereto, Applicants have amended Claim 15 to specifically indicate that the hybridoma is selected from the group consisting of FERM BP-5248 (AJvW-2), and FERM BP-5250 (AJvW-4), "or a variant of said hybridoma."

Applicants also wish to direct the Examiner attention to Claim 1 of US 5,916,805 (grandparent application of the present application) in which the Office has already found the phrase "or a variant of said hybridoma" to be definite and free of the art. Much as was found by the Office in US 5,916,805, the presently claimed invention is also free of the art of record, specifically Benson et al, Fujimura et al, and Scarborough.

Applicants request withdrawal of this ground of rejection.

The rejection of Claims 15-21 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Regarding criticism (A) raised by the Examiner, the term “variant” relates to the hybridoma and seeks to retain coverage of monoclonal antibodies resulting from any variation in the progeny of these hybridomas. To clarify the present invention and the scope entitled thereto, Applicants have amended Claim 15 to specifically indicate that the hybridoma is selected from the group consisting of FERM BP-5248 (AJvW-2), and FERM BP-5250 (AJvW-4), “or a variant of said hybridoma.”

Turning to criticism (B), Applicants have removed the objectionable language from Claim 15.

Finally, in criticism (C), the Examiner has requested clarification of where support for present Claims 15-21 can be found. Applicants point to page 17, line 21 to page 18, line 22 and page 19, line 7 to page 27, line 19 of the specification as an example of where support can be found. Further support for Claims 15-21 can be found in the Examples of the present specification.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The Examiner has objected to Claims 17 and 19 under 37 C.F.R. §1.75 as being substantial duplicates of Claims 18 and 20, respectively. Applicants traverse this ground of objection.

As has been stated above, the variant in question relates to the hybridoma and seeks to retain coverage of monoclonal antibodies resulting from any variation in the progeny of these hybridomas. In other words, within the scope of the present invention are monoclonal antibodies that are derived from the parental hybridoma, but have slight modifications due to

hybridoma modifications along the parental lineage. To ensure clarity of the present invention, Claim 15 has been amended to underscore the differentiation between these terms.

Applicants submit that the claims are appropriate within the context of 37 C.F.R. §1.75.

As such, Applicants request withdrawal of this ground of objection.

The objection to the specification for failure to include a "Brief Summary of the Invention" is obviated by insertion of the same into the specification beginning on page 9, following line 12. Applicants further note that the specification has been amended to update the status of US 09/299,016 (now U.S. Patent No. 6,280,731). In addition, the specification has been amended to correct the errors pointed out by the Examiner at page 21, line 14 and page 25, line 2. Applicants note that in order to ensure consistency within the present family of patents, no further amendment is believed to be necessary and/or required.

Acknowledgment that these objections have been withdrawn is requested.

The statutory double patenting rejection of Claims 17-20 over Claims 3, 5, 13, 15, 18, and 20 of U.S. 5,916,805 is obviated by amendment.

Applicants note that the claims have been amended to claim a pharmaceutical composition containing a pharmaceutically suitable carrier and the claimed monoclonal antibody. In contrast, U.S. 5,916,805 claims monoclonal antibodies and antithrombotic agents. Accordingly, Claims 17-20 of the present application cannot qualify as the "same invention" as Claims 3, 5, 13, 15, 18, and 20 of U.S. 5,916,805.

Applicants request withdrawal of this ground of rejection.

The Examiner has rejected Claims 17-21 under the judicially created doctrine of obviousness-type double patenting over Claims 1-20 of U.S. 5,916,805 and over Claims 1-4 of U.S. 6,280,731.

Applicants submit herewith a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c), disclaiming the terminal part of any patent granted on the above-captioned application, which would extend beyond the expiration date of the full statutory term as presently shortened by any terminal disclaimer of U.S. 5,916,805 and of U.S. 6,280,731.

Applicants note that the filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection.

Applicants respectfully request withdrawal of the rejection based on the judicially created doctrine of obviousness-type double patenting.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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